DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HEALTH CARE FACILITY
LICENSURE & CERTIFICATION
99 Chauncy Street
Boston, MA 02111

ADULT DAY HEALTH APPROVED TESTS FORM

Submit this form, together with a CMS Form 116, when an Adult Day Health program wishes to perform waived urinalysis tests, waived glucose tests, and waived PT/INR tests under orders by a primary care physician. Submit the completed form to:

Licensure Coordinator
Department of Public Health – DHCFLC
99 Chauncy Street, 11th Floor
Boston, MA 02111

A. APPLICANT INFORMATION:

1._____
Program Name (name by which you will do business)

2._____
Program Address (Street, City/Town, ZIP

3._____
Name of Contact Person for Application Process

4. _____ 5. _____
Email Address of Contact Person for Application Process Telephone Number

6. CLIA Certificate of Waiver:

___ Already obtained - CLIA Number: _____ (Copy Attached).
___ Completed CMS 116 attached.[1]

7. Tests to be performed:

____ Urinalysis, CLIA-waived ____ Glucose, Fingerstick, CLIA-waived

____ PT/INR, Fingerstick, CLIA-waived (see additional requirements, reverse)

8. Program Attestation:

____ Oversight will be provided by registered nurses.

____ Performance of such tests shall only be performed by licensed nurses who have been trained and determined competent Competency is required to be updated annually.

_____ Test systems to be used are limited to those the Food and Drug Administration (FDA)[2] has determined to be waived based on approval of manufacturers' applications for test system waiver.

_____Will follow all manufacturers' instructions for performing the test in the product insert from "intended use" to "limitations of the procedure".

____ Will notify Clinical Lab Program of any changes in ownership, name, address or CMS-116 CLIA reported lab director within 30 days.

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[1] For CMS-116 and directions see: http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
[2] For the FDA list of waived tests see: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/search.cfm

If the program will be conducting PT/INR, fingerstick, CLIA-waived tests, the following are additional requirements that must be complied with:

1. Quality Control (QC) must be performed; and,
2. must be within manufacturer's specified acceptable range (Plus or minus 2 Standard Deviations of the calculated mean) before any patients can be tested.
3. QC of each instrument must be demonstrated with either:
    a. two levels of external liquid controls each day of testing; or,
    b. two levels of control (one or both of which can be electronic and/or internal) each day of testing and two levels of external liquid controls weekly
4. for instruments for which external QC materials are not available:
    i. manufacturer's documentation/studies that demonstrate internal QC performance acceptability without the use of external quality controls; and,
    ii. the internal QC features must monitor conditions of storage and use and must demonstrate reagent stability. Patient testing cannot be reported if these are compromised.
5. documentation that the controls function as expected each day of use;
6. Remedial actions must be documented.
7. The manufacturer's performance specifications must be verified for each new instrument prior to testing, e.g. correlation vs. reference laboratory.
8. Proficiency Testing:
    a. The laboratory must be enrolled in an approved Proficiency Testing (PT) program, if one is available. Documentation of remedial action is required for every PT result that is less than 100%. A copy of the action plan must be sent to the CLP. Testing must cease immediately if it has an unsuccessful PT performance for two in a row or two out of three PT testing events. Unsuccessful performance is defined as failure to attain a minimum score of 80% for an analyte, test, or specialty. Reinstatement of testing cannot begin until the facility has documentation of corrective action, including retraining if necessary, and successfully completed two external proficiency test events.
    b. If there is not PT available, an acceptable alternative proficiency program can be used. Compare test results with another CLIA certified laboratory by using a valid method evaluation comparison system is acceptable. On a quarterly basis test 5 patients; within one hour draw the same patients and send the drawn specimens to a reference lab. All five results must be within acceptable limits in order to be considered a passing score.
9. The facility must maintain a log for each instrument that includes patient name, date/time of testing, test result, QC tests for the day, lot number of reagents, expiration date of reagents, QC ranges and results

_____ Date: _____

Signature of Applicant or Applicant's authorized representative

_____

Typed/printed name of Applicant or Applicant's authorized representative